

231A. The spread on Aranesp was created at the time of its introduction, and Amgen has published an AWP that created at times at least a 40% spread between the estimated cost to a dispenser and AWP. Given the significant cost of Aranesp this is about \$300 per unit for most NDCs. If a typical treatment involves two doses twice a month for a three- to four-month period, the cost of this spread is \$1800 - \$2400 per patient. For a Medicare patient this could increase co-payments by \$360 - \$480.

231B. The use of rebates and off-invoice discounts did not start in 2003 but occurred shortly after Aranesp was introduced in 2002. The allegation is based on (a) the fact that the competition between Amgen and Ortho existed before 2003, (b) that Ortho was heavily engaged in its own conduct directed at marketing the spread and Amgen needed to respond in kind, (c) Amgen was offering "introductory" discounts that inflated AWP, and (d) as noted above Amgen sales representatives were armed with calculations showing the profit created by the Aranesp spread. Ortho, at national sales meetings, authorized its sales and marketing representatives to provide free samples as a means of lowering acquisition costs to providers. Ortho also used inducements such as educational and promotional grants to win over clinics and other providers and as credit memos which were inducements for a clinic or provider to use Procrit exclusively. Amgen sales representatives learned of these efforts and reacted to them by offering inducements of their own. These inducements included rebates based upon volume used by the practitioner.

241. Amgen's efforts at using inflated AWP's to increase market share were successful as Aranesp sales have steadily increased.

232A. Amgen's AWP-related manipulation did not stop at Aranesp. Prior to its acquisition of Immunex, Amgen competed with Immunex with respect to its drug Neupogen and Immunex's Leukine. Documents produced by Immunex reveal that Immunex was marketing Leukine based on the spread, promoting its spread of \$80.60 per vial as an advantage over

Amgen's \$51.61 spread per vial. At the time of this spread marketing by Immunex, Amgen published an AWP for Neupogen of roughly \$263.30, and was selling its product to doctors at \$201.16. This created a spread of 31% off of AWP which, given the high price of each vial, would have a substantial impact on co-payors and third-party payors, and provided a handsome profit to providers.

232B. Amgen's use of the spread did not go unnoticed by competitors. In an internal memorandum, employees of a competitor, Centecor, wrote in the context of "reimbursement issues" that doctors have a "fear of audit and not being perceived as infusing only for profit," *i.e.*, using infusion where other treatments were available, but noted that Amgen had no issues in encouraging oncologists to choose drugs based on the spread:

We need to do a stronger job up front driving home the patient benefit of PMP. One of the other reasons I see doctors hitting a point and not moving forward is fear of audit and not being perceived locally as infusing only for profit. An example of what goes on in other specialties might be of benefit – personally I would use an *Amgen* or Immunex oncology product and show the AWP versus payment.

We don't need to make this a big production—if you put the slide up with the product and company the attendees can connect the dots.

242. The foregoing e-mail is in effect competitor intelligence confirming that Amgen was marketing the spread on its products sold to oncologists, which include Aranesp, Neulasta and Neupogen.

233A. Spreads created for Neupogen are set forth below for a 300ml dose. Not only are the spreads sizable, but reported AWP's increased faster than the real AWP, thus making the reported AWP's in later years even more inflated. This increase in spread is the direct result of an effort to induce physicians to use Neupogen due to the increase in the spread:

<u>Year</u>	<u>Reported AWP</u>	<u>Real AWP</u>	<u>Spread in Dollars</u>	<u>Percentage</u>
1997	\$161.30	\$125.09	\$36.21	28
1998	\$165.30	\$130.02	\$35.28	27
1999	\$180.40	\$134.81	\$45.91	34
2000	\$188.50	\$140.49	\$39.88	28
2001	\$197.80	\$148.62	\$49.18	33
2002	\$207.50	\$149.60	\$57.90	38

233B. Spreads for the 10,000 u/ml ten pack for Epogen were historically approximately 33%, but beginning in January 2000 Amgen implemented a series of AWP increases so that by 2002 the spread increased to 42%. The increase in spread was designed to increase market share.

243. AWP's for the 4,000 units/ml of Epogen were also inflated with spreads between 92% and 105%. AWP's for this drug/dose increased while costs to the provider decreased. Similarly, the ten pack 4,000 units/ml dose started in 1997 with a spread of 26% that increased to 47% over time.

234A. Amgen has also caused artificially inflated AWP's to be published for its top-selling drug Enbrel. Originally, the spread between AWP and acquisition cost was 25%. This spread has steadily increased over time such that for some doses, the spread is 32% to 40%. Amgen has created this spread to encourage promotion and use of Enbrel by those in the distribution chain.

6. Amgen Rebates on Epogen

2334B. In addition to marketing the spread, Amgen has utilized other impermissible inducements to stimulate sales of its drugs. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price.

244. A 1993 OIG Report detailed how Amgen gave substantial year-end rebates to its customers based on their purchases of Epogen. The report noted that Medicare and Medicare beneficiaries did not receive the benefit of any rebates; all monies remained with the provider.

There was no way to provide for any rebates on Medicare claim forms, and Amgen's rebates were not provided until year-end:

[T]he effect of the rebates is that it reduces the actual cost of EPO to a dialysis facility, thus increasing their gross profit. Presently, the rebates represent price reductions which benefit the facilities exclusively.

("Review of Epogen Reimbursement," (OIG A-01-02-00506 at 7-8)).

235A. By utilizing hidden inducements, Amgen provided purchasers with substantial discounts meant to gain their patronage while maintaining the fiction of a higher wholesale price.

245. Amgen's scheme to inflate its reported AWP and market the resulting spread to increase the market share of its drugs and its use of hidden rebates and financial inducements to its customers has resulted in excessive overpayments by Plaintiffs and the Class.

7. Amgen Concealed Its AWP Manipulation

236A. Amgen deliberately acted to conceal its fraudulent reporting and marketing of the AWP spread. For example, as noted above, Amgen gave rebates to its Epogen customers which effectively lowered the true price charged. When OIG asked Amgen for data on its total sales or the total amount of Epogen rebates, Amgen refused to provide such data. ("Review of Epogen Reimbursement," (OIG A-01-02-00506 at 7-8)).

246. In September 2001, the GAO reported that epoetin alfa accounted for the second highest percentage of Medicare expenditures on drugs in 1999, accounting for 9.5% of spending for prescription drugs by Medicare in 1999 and for 3.4% of all Medicare allowed services.

237A. As set forth above, Amgen's scheme to inflate its reported AWP and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

C. AstraZeneca

247. AstraZeneca has engaged in an ongoing deliberate scheme to inflate AWP. The drugs at issue for this defendant are identified in Appendix A and summarized below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
ASTRAZENECA	Accolate	zafirlukast	Leukotriene Antagonist (Respiratory Agent) Used in the treatment of asthma
	Armindex	anastrozole	Antiestrogen (Antineoplastic: Hormonal Agonist/Antagonist) Used in the treatment of breast cancer in postmenopausal women
	Atacand	candesartan cilexetil	Angiotension II Receptor Antagonist (Cardiovascular Agent) Used in the treatment of hypertension
	Atacand HCT	candesartan cilexetil-hydrochlorothiazide	Angiotension II Receptor Antagonist With Diuretic (Cardiovascular Agent) Used in the treatment of hypertension
	Casodex	bicalutamide	Antineoplastic Used in the treatment of prostate cancer
	Diprivan	propofol	General Anesthetic Used in the induction or maintenance of anesthesia as part of balanced anesthetic technique
	Entocort	budesonide	Glucocorticoid Used in the treatment of Crohn's disease
	Nexium	esomeprazole magnesium	Proton Pump Inhibitor (Gastrointestinal Agent) Used in the treatment of heartburn and erosive esophagitis
	Nolvadex	tamoxifen citrate	Antiestrogen (Antineoplastic: Hormonal Agonist/Antagonist) Used in the treatment or prevention of breast cancer
	Prilosec	omeprazole	Proton Pump Inhibitor (Gastrointestinal Agent) Used in the treatment of gastric and duodenal ulcers, gastroesophageal reflux disease and erosive esophagitis
	Pulmicort	budesonide (inh)	Glucocorticoid Used for maintenance treatment of asthma
	Rhinocort	budesonide (nasal)	Glucocorticoid Used in the treatment of allergic rhinitis
	Seroquel	quetiapine fumarate	Antipsychotic Agent (Psychotherapeutic Agent) Used in the treatment of schizophrenia
	Toprol	metoprolol succinate	Beta Adrenergic Blocking Agent (Cardiovascular Agent) Used in the treatment of hypertension, angina pectoris and heart failure

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	Zestril	lisinopril	Angiotension Converting Enzyme Inhibitor (Cardiovascular Agent) Used in the treatment of hypertension and heart failure
	Zoladex	goserelin acetate	Gonadotropin Releasing Hormone Analogue (Antineoplastic: Hormonal Agonist/Antagonist) Used in the treatment of prostate and advanced breast cancer
	Zomig	zolmitriptan	Serotonin Receptor Agonist (Migraine Preparation) Used in the treatment of migraines

1. AstraZeneca Has Been the Target of a Government Investigation

248. In connection with its scheme to inflate AWP's, AstraZeneca has been investigated by the United States Department of Justice. In January 2002, a federal grand jury in Wilmington, Delaware returned an indictment accusing a New Jersey doctor of conspiring with AstraZeneca to resell free samples of Zoladex® that AstraZeneca sales representatives had given the doctor. The indictment alleges that AstraZeneca (i) sold Zoladex® to the New Jersey doctor and others at prices substantially below the AWP reported by AstraZeneca, and (ii) provided the New Jersey doctor with materials showing how much more profit he could make by using Zoladex® instead of its competitor, Lupron®.

249. In response to the government's subpoena, AstraZeneca appears to have produced documents related to Zoladex only.

2. AstraZeneca's Definition and Understanding of AWP

250. In AstraZeneca's Guide to Coverage and Reimbursement, AstraZeneca defines AWP as follows:

Average Wholesale Price (AWP): The composite wholesale price charged on a specific commodity that is assigned by the drug manufacturer and is listed in either the Red Book or Blue Book. AWP is often used by third-party payers as a basis for reimbursement.

(AZ0052597) (Confidential). Thus, by its own definition, AstraZeneca recognizes that: (i) AWP should be an average of actual wholesale prices; (ii) the drug manufacturers control the published AWP; and (iii) the published AWP directly affect the payments made by the Class.

3. AstraZeneca Controls the Published AWP for Its Products

251. AstraZeneca has controlled and set the AWP for its pharmaceutical products through direct communications with industry compendia during the Class Period. In one internal marketing memorandum, AstraZeneca recommended:

We take a price increase in December 1995. By doing this, we can inform the Red Book of this increase and it will go into the Red Book for January 1996. This is critical, so that the state Medicare carriers can recognize our new price in January. Typically, the state carriers use the January Red Book and the July Red Book for their reimbursement price of Medicare reimbursed products. Last year when we took the price increase in February there were some Medicare carriers who did not change their reimbursement price until September. Also TAP notifies Red Book 1 month before the price change. We are at a competitive disadvantage with our audience.

(AZ0021838) (Highly Confidential).

4. AstraZeneca's AWP Manipulation Benefited Providers at the Expense of the Class

252. The purpose of AstraZeneca's manipulation was to increase the spread in order to maximize the profit to providers and other intermediaries at the expense of Plaintiffs and the Class.

a. In one internal marketing memorandum, AstraZeneca recognized the profits to providers from the inflation of AWP: "The market we are in wants a more expensive Zoladex, because the doctor can make more money." (AZ0021838) (Highly Confidential).

b. Similarly, in its agreements with PBMs, AstraZeneca guaranteed that it would maintain a spread between AWP and AWC (average wholesale cost) in order to ensure a profit to PBMs at the expense of the Class. (AZ0036207) (Highly Confidential). For example, in its agreement with Caremark, AstraZeneca stated:

ZENECA WILL REIMBURSE CAREMARK FOR THE DIFFERENCE BETWEEN THE AMOUNT COLLECTED BY CAREMARK ON EACH PATIENT UNIT SOLD AND AWP AT THE TIME THE UNIT WAS DISPENSED. CAREMARK WILL HAVE EXERCISED BEST EFFORTS TO COLLECT THE FULL AWP FROM THE 3RD PARTY PAYER AND THE PATIENT PRIOR TO SUBMISSION TO ZENECA.

(AZ0036208) (Highly Confidential).

c. AstraZeneca recognized that its practices were at the expense of the Class:

BECAUSE OF OUR STEEP DISCOUNTING, NEARLY HALF THE PROFIT TO BE REALIZED WITH ZOLADEX IS PAID BY MEDICARE. AND SINCE MEDICARE IS THE QUICKEST AND MOST DEPENDABLE PAYOR, THIS WAS SEEN AS AN ENORMOUS BENEFIT. THE OTHER HALF OF THE PROFIT WAS FROM THE PATIENT CO PAY OR SECONDARY INSURANCE

(AZ0037011) (Highly Confidential).

5. AstraZeneca Manipulated and Marketed the AWP for Zoladex

253. AstraZeneca stated an inflated AWP for Zoladex and marketed the resulting spread during the Class Period. AstraZeneca's documents reveal an intense competition with TAP Pharmaceuticals and its drug Lupron, focusing primarily on the spreads available to physicians between Zoladex and Lupron.

254. For instance, one internal chart touts the greater spread that can be reaped from the inflated AWP for Zoladex over the AWP for Lupron:

	AWP	AWP minus 5%	Current Cost (1 depot)	Return to Practice 1 depot	Current Max Discount 29.5% vs 50%	Return to Practice at Max
Lupron 3-month depot	\$1,622.68	\$1,541.55	\$1,297.50	\$244.05	\$915.00	\$626.55
Zoladex 3-month depot	\$1,231.53	\$1,169.95	\$985.22	\$184.73	\$492.61	\$677.34

(AZ 0055816) (Highly Confidential).

255. Another document announcing new pricing for Zoladex states:

With a purchase of 72+ depots of ZOLADEX and the additional 2% for paying within 30 days yields the doctor a \$133.67 profit

margin with ZOLADEX vs \$133.50 with a purchase of 101+ depots of Lupron. For those offices that purchase between 60-100 depots of Lupron monthly, they can increase their profit margin greatly by purchasing ZOLADEX.

(AZ 0037019) (Highly Confidential).

256. Moreover, AstraZeneca repeatedly tried to educate providers regarding the Medicare reimbursement system and the benefits to the providers for Zoladex utilization. For example in a document sent to providers AstraZeneca states:

The following is a cost comparison of Zoladex® vs. Lupron® 7.5 mg when Zoladex® is purchased under the buying power of the Urology Purchasing Group, St. Louis, Mo. The calculations reflect prices/discounts effective as of 2/1/94.

	ZOLADEX	LUPRON			
Quantity	1	1-11	12-25	26-50	Year Office
Direct Drug Cost	\$245.97	\$371.00	\$360.99	\$352.50	\$
Medicare & Claim	\$344.76 x 80%	\$463.75 x 80%	\$463.75 x 80%	\$463.75 x 80%	\$463.75 x 80%
Medicare Payment to MD	\$275.81	\$371.00	\$371.00	\$371.00	\$371.00
Patient / 3rd Party Payment*	\$344.76 -275.81 \$ 68.95	\$463.75 -371.00 \$ 92.75	\$463.75 -371.00 \$ 92.75	\$463.75 -371.00 \$ 92.75	\$463.75 -371.00 \$ 92.75
Medicare Claim Direct Drug Cost	\$344.76 -245.97	\$463.75 -371.00	\$463.75 -360.99	\$463.75 -352.50	\$463.75 -
Total Profit Per Injection	\$ 98.79	\$ 92.75	\$103.75	\$111.25	
Difference		\$ 6.04	\$ 4.96	\$ 12.46	\$
Percent Profit per Injection	40%	25%	29%	32%	%
Additional Cost outlay of Lupron vs Zoladex (Direct Cost vs Direct Cost)		\$125.03	\$114.03	\$106.53	\$

ILLUSTRATION: If your office uses between 12 and 25 Lupron® units per month, your total "profit" per injection, over Zoladex, is \$4.96 but your additional outlay per Lupron injection is \$114.03. This represents and unnecessary tie up of corporation monies. Based on 12 Lupron injections per month, your office has "tied up" \$1,368.36 to achieve a "profit" of \$59.52. In this example, Zoladex represents a 40% return on investment vs. 29% for Lupron.

* Calculations assume a 100% collection of monies from patient or 3rd party. If Lupron® is used instead of Zoladex® and the 20% is not collected, then the office has lost \$23.20 per injection (\$92.75 - \$68.95 = \$23.80).

01-26-0413

(AZ0046085) (Highly Confidential).

257. Internal AstraZeneca documents reveal that AstraZeneca was directly marketing the spread to physicians. A memo announcing price changes for Zoladex states:

We have raised AWP and AWC by 7% and have increased our discount level higher at all purchasing tiers.

Pricing on Zoladex 3-month is as follows:

Discount		AWP	Cost
1-5 depots	0	1206.49	966.79
6-11 depots	11	1206.49	860.44
12-23 depots	15	1206.49	821.77
24-47 depots	17	1206.49	802.44
48-59 depots	20	1206.49	773.43
60-71 depots	22	1206.49	754.10
72-96 depots	24	1206.49	734.76
96-191 depots	25	1206.49	725.09
192 +	30	1206.49	676.75

Zoladex AWP has been priced at a 5% premium above 3 times the Zoladex 1-month depot. The discount levels have been increased also.

(AZ 0024566-67.)

258. Thus, at the same time AstraZeneca was raising the AWP for Zoladex, it was lowering the real price to providers (by giving bigger discounts), which served to widen the spread.

259. Another document sets forth the difference between the purchase price and the AWP at various volume levels. Note that even with no volume discount, a provider is still making at least a \$71.00 profit per unit on Zoladex ($\$358.55 - 286.84 = 71.71$):

NEW LOWER CASE QUANTITY DISCOUNT
ZOLADEX PRICING

UNITS AWP COST DISCOUNT LESS 2%

1-5	\$358.55	\$286.84	0%	\$281.10
6-11	\$358.55	\$269.63	6%	\$264.24
12-23	\$358.55	\$261.02	9%	\$255.80
24-47	\$358.55	\$252.42	12%	\$247.37
48-59	\$358.55	\$243.81	15%	\$238.93
60-71	\$358.55	\$235.21	18%	\$230.50
72+	\$358.55	\$229.47	20%	\$224.88

(P003060.)

260. The same document goes on to tout the practice's ability to make more profit, or return on investment, by exploiting the AWP scheme:

Thank you for your time and listening ear on Monday, April 17.
As discussed, I am offering a proposal to switch Lupron patients to Zoladex. Zeneca Pharmaceuticals now has new volume pricing, with a 20% maximum discount, for Zoladex. What this will offer the practice is an opportunity to save money, realize a better return on investment, achieve the same profit you currently have with our competitor and free up a substantial amount of working capital. Zoladex will also save the patient money and the system money.

Based on a comparison of Zoladex and Lupron, if 480 depots are used annually Zoladex will save the practice \$57,177.60 a year. Your dollar return to the practice is now slightly higher with Zoladex. This rate of return for Zoladex is now 59% compared to Lupron's 39%

(P003058.)

261. Another AstraZeneca document even more explicitly demonstrates to providers how they can profit from the AWP scheme, in excess of \$64,000 per year:

ZOLADEX			
Direct Pricing	Medicare AWP	\$\$Return / % Return	
72+ \$224.88	\$358.55	\$133.67	59%
72x\$224.88=\$16,191.38	72x\$358.55=\$25,815.60	\$9,624.24	59%
<i>based on your use of 480 depots annually, with our 2% discount these are the comparisons</i>			
\$107,942.40	\$172,104.00	\$64,161.60	59%

(P003058.)

262. According to a September 2001 GAO report, the discount from AWP for medical providers who purchased AstraZeneca's Zoladex and billed Medicare was between 21.9% and 22.3%. ("Payments for Covered Outpatient Drugs Exceed Providers' Cost, Sept. 2001")

(P005546-78).)

263. AstraZeneca, through its employees and agents, also provided millions of dollars worth of free samples of its drugs to providers. The free samples would be used to offset the total cost associated with purchases of its drugs, thereby increasing the spread, while also concealing the actual cost of the drug from Plaintiffs and the Class. Moreover, at least as to Zoladex®, AstraZeneca sales representatives specifically told providers that they could and should bill for the free samples.

264. A written proposal from AstraZeneca Sales representative Randy Payne dated July 17, 1995 encourages a urology practice to switch all of their patients to Zoladex and states: “AS AN ADDED INCENTIVE, ZENECA WILL PROVIDE YOU WITH 50 FREE DEPOTS (over \$11,900 worth of product) FOR THE INITIAL CONVERSION TO ZOLADEX.” (P003059.)

265. As set forth above, AstraZeneca’s scheme to inflate its reported AWP’s for Zoladex, market the resulting spread, and channel to providers “free” goods – all in order to increase the market share of its drugs – has resulted in excessive overpayments by Plaintiffs and the Class.

D. The Aventis Group (Aventis, Pharma, Hoechst and Behring)

266. Aventis engages in an organization-wide and deliberate scheme to inflate AWP’s. Aventis has stated fraudulent AWP’s for all or almost all of its drugs, including those set forth below. The specific drugs of Aventis for which relief is sought in this case are set forth in Appendix A and are as follows:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
AVENTIS GROUP (Aventis, Pharma, Hoechst and Behring)	Allegra	fexofenadine	Antihistamine Used for the relief of symptoms of seasonal allergic rhinitis
	Allegra-D	fexofenadine pseudoephedrine	Antihistamine Used for the relief of symptoms of seasonal allergic rhinitis

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	Amaryl	glimepiride	Antidiabetic Used to lower blood glucose in Type II diabetes patients
	Anzemet	dolasetron mesylate	Antineoplastic Used to prevent nausea and vomiting after chemotherapy or operation
	Arava	leflunomide	Antirheumatic Used in the treatment of active rheumatoid arthritis
	Azmacort	triamcinolone aceonide (inh)	Steroidal Anti-Inflammatory Agent (Respiratory Agent) Used for maintenance treatment of asthma
	Calcimar	calcitonin salmon	Parathyroid Agent Used in the treatment of blood calcium levels and to increase the level of calcium in the bones
	Carafate	sucralfate	Duodenal Ulcer Adherent Complex (Gastrointestinal Agent) Used in the treatment and maintenance therapy of duodenal ulcer
	Cardizem	diltiazem	Calcium Channel Blocker (Cardiovascular Agent) Used in the treatment of angina and hypertension
	Gammar P.I.V.	immune globulin	Immunizing Agent Used as a maintenance therapy in patients with compromised immune systems
	Intal	cromolyn sodium	Antiasthmatic Used to treat allergic rhinitis and severe perennial bronchial asthma
	Nasacort	triamcinolone acetoneide (nasal)	Steroidal Anti-Inflammatory Agent (Nasal Preparation) Used for nasal treatment of allergic rhinitis symptoms
	Taxotere	docetaxel	Antineoplastic Used in the treatment of breast or lung cancer after failed chemotherapy
	Trental	pentoxifylline	Blood Viscosity-Reducing Agent (Blood Modifier) Used to improve the flow of blood through blood vessels

1. Aventis Has Been the Target of Government Investigations

267. In connection with its scheme to inflate AWP's, Aventis has been investigated by the United States Department of Justice, the Office of Inspector General of the Department of Health and Human Services, the Commerce Committee of the U.S. House of Representatives, the Attorney General for the State of Texas, the Attorney General for the State of California, and the State of California Department of Justice Bureau of Medi-Cal Fraud and Elder Abuse.

2. Aventis' Definition and Understanding of AWP

268. Internal documents recently produced by Aventis reveal the definition of AWP used and understood by Aventis and its predecessor companies. Specifically, a November 1992 internal newsletter at Armour Pharmaceutical Company (a predecessor company to Centeon LLC, later known as Aventis Behring) states:

"AWP" is common language among insurance carriers (state, federal and private). The acronym stands for Average Wholesale Price. AWP's are set by manufacturers as a "suggested retail" for the products they produce. *These figures represent a reasonable profit margin to healthcare providers and as such are widely referenced by insurance carriers when setting reasonable and customary rates of reimbursement.*

Average Wholesale Prices are printed in Red Book Drug Topics and Blue Book. Both serve as data resources to all state Medicaid programs. Each publication lists the drugs by brand name in alphabetical order with its corresponding descriptions.

(ABAWP 008990-91) (Highly Confidential) (emphasis added).

269. Aventis possessed the *Red Book's* definition of Average Wholesale Price:

Average wholesale price (AWP) is the standardized cost of a drug, which managed care plans frequently use for determining drug benefits. The AWP is determined through reference to a common source of price information, such as the American Druggist's *Blue Book*, which lists the costs charged for an undiscounted drug to a pharmacy by a large group of pharmaceutical wholesale suppliers. AWP's are set by pharmaceutical manufacturers and supplied to all pricing data banks for publication.

(ABAWP 012067) (Highly Confidential).

3. Aventis Controls the Published AWP for Its Products

270. Aventis controlled and set the AWP for its pharmaceutical products through direct communications with industry compendia during the Class Period.

a. For example, on December 29, 1997, Rhone-Poulenc Rorer (a subsidiary of Rhone Poulenc SA, which merged with Hoechst AG to form Aventis in 1999) submitted a list of AWP price increases effective January 1, 1998 to both Medi-Span and First Data Bank. Aventis instructed Medi-Span and First Data Bank to “change [their] records accordingly to reflect the new prices.” (AV-AAA-001054) (Confidential). Similar letters requesting price changes for 1999 were sent to Medi-Span and First Data Bank by Aventis on December 29, 1998. (AV-AAA-001047) (Highly Confidential), (AV-AAA-001050) (Highly Confidential), and price changes for 1997 on December 23, 1996 (AV-AAA-001066) (Highly Confidential).

b. An April 1, 1998 letter from Centeon notifies Medical Economics (the *Red Book*) that effective April 1, 1998, it “has raised AWP pricing” for Bioclade and Monoclade. (ABAWP 005314) (Highly Confidential).

4. Aventis’ AWP Manipulation Benefited Providers at the Expense of the Class

271. The purpose of Aventis’ manipulation was to increase the spread in order to maximize the profit to providers and other intermediaries at the expense of Plaintiffs and the Class.

272. Aventis knew that AWP manipulation, and the related marketing of an AWP spread, was improper. An internal Aventis (Centeon) document, in pertinent part, states – in large, bold print:

ATTENTION!

SELLING AGAINST AWP

This is not an option.

Traditionally, some manufacturers have promoted differences in AWP as a means to sell their products. Centeon does not do this,

and we hope to hear from you if you learn that any other manufacturer (sic) are using this tactic.

Some pharmaceutical manufacturers set high AWP's as a means of securing market shares for their drugs. Although not illegal, the intensity of government scrutiny of this and other pharmaceutical manufacturer pricing practices is increasing. The inspector general is looking at prices for big-ticket drugs

At the risk of being redundant it is imperative to stress that AWP can not (sic) be used in the content of selling any of our products. If you are made aware, either orally or through written correspondence, of any manufacturer using this form of sales tactic immediately report such findings to Gene Hull and appropriate steps will be taken.

(ABAWP 000855) (Highly Confidential).

273. Nonetheless, Aventis (Centeon) routinely promoted differences in AWP's in marketing its numerous products. In seminar materials used in conjunction with an "Oncology University Anzemet Workshop" held in 1998, Aventis explained to attendees how its AWP spread could be exploited. Aventis offered the following definition and example of AWP spread:

SPREAD

- Difference between acquisition cost (AC) and reimbursement (Profit, Margin, etc.).
- Example for Anzemet
 - AC = \$68 for 100 mg vial
 - AWP = \$166.50
 - AWP - 5% = \$158.18
 - 80/20 = \$126.54/\$31.64
 - Spread = \$58.54 + \$31.64 = \$90.18

(AV-AAA-02242-56) (Highly Confidential).

274. Aventis, through its employees and agents, also provided free samples of its drugs to providers. (ABAWP 000089) (Highly Confidential) (ABAWP 000811) (Highly Confidential). The free samples would be used to offset the total cost associated with purchases of its drugs,

thereby increasing the spread, while also concealing the actual cost of the drug from Plaintiffs and the Class. In fact, a 1995 "SALES AND FREE GOODS STATUS" memo reveals that Aventis (Armour) issued millions of "free goods units" to a single customer alone. (ABAWP 000220-25) (Highly Confidential).

275. Further, just as Aventis motivates providers to administer drugs based on the AWP, Aventis rewards PBMs based on the degree of influence they exert to drive utilization of Aventis products. (AV-AAA-000197-99) (Highly Confidential).

5. Specific Aventis AWP's Documented by the DOJ

276. In a report published by the DHHS (AB-00-86), the DOJ documented at least 15 instances where the published AWP's for various dosages of 4 drugs manufactured by Aventis were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the 4 drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by Aventis in the 2001 *Red Book*.

Drug	2001 <i>Red Book</i> AWP	DOJ Determined Actual AWP	Difference	Percentage Spread
Anzemet Injectable (dolasetron mesylate)	\$166.50	\$74.08	\$92.42	125%
Factor VIII/ Bioclone	\$1.25	\$.91	\$.34	37%
Factor VIII/ Helixate	\$1.18	\$.78	\$.40	51%
Gammar (immune globulin)	\$400.00	\$296.67	\$103.33	35%

(P006299-P006316).

277. An OIG report (*see* "Medicare Reimbursement of Prescription Drugs," OEI-03-00-00310, Jan. 2001) further revealed that: (i) the AWP for all immune globulin 5 mg doses listed in the 1997 *Red Book* were inflated by an average spread of 32.21%; (ii) a 10 mg dose of Anzemet had a Medicare Median of \$14.82 and a Catalog Median of \$8.29, resulting in a spread

of 78.76%; and (iii) a 20 mg dose of Taxotere had a Medicare Median of \$283.65 and a Catalog Median of \$8.29, resulting in a spread of 18.75%. (P006398-006424).

6. Additional Evidence Concerning Anzemet

278. Aventis distributed a "Reimbursement Spreadsheet" to be utilized by its sales personnel to demonstrate to "private practice office" customers the "financial advantages" of its drug, Anzemet, compared to Zofran and Kytril based on Aventis' established AWP and acquisition price (total reimbursement through Medicare). (AV-AAA-001190-93) (Highly Confidential). Aventis also communicated to its sales staff on December 7, 1998 that "Anzemet still [held] the advantage on spread" following a Kytril price increase. (AV-AAA-002291) (Highly Confidential).

279. Another Aventis internal document also addresses how a particular Aventis customer might increase its margin choosing Anzemet over the competition:

Cost and Reimbursement: OnCare has negotiated a very favorable contract with Hoechst Marion Roussel [an Aventis predecessor company], manufacturer of Anzemet. Our cost from OTN for the Anzemet 100 mg/ml vial is reduced from approximately \$70 ea. to \$62.50. In addition there will be quarterly rebates further reducing the cost to \$61.25. The AWP is \$149.88, making the margin \$88.63. Additional returns can be realized by using 1.8 mg/kg as recommended in the package insert. For example, for a patient weighing 70Kg, the dose is 126 mg, requiring 2 vials. Since the vial is single use, you may bill for both vials: total cost is \$122.50, the AWP is \$299.76, the net is \$177.26 (assuming reimbursement at AWP). By comparison the current margin for 0.7 of Kytril is \$54.89. For 1 mg it is \$78.42. If there is a price increase in 1999 (which we expect) our prices are protected, however the AWP will go up, further increasing the margin. The contract makes Anzemet the preferred 5-HT3 antiemetic drug for OnCare.

(AV-AAA-001523) (Highly Confidential). Other customers received promotional materials reflecting a significant spread between the unit price and AWP for Anzemet – and touting a "Reimbursement and Patient Assistance Program Hotline." (AV-AAA-001619-23) (Confidential).

280. A government investigation revealed similar inflated pricing implemented by Aventis with respect to the injectable form of Anzemet. In a September 28, 2000 letter to Alan F. Holmer, President of the Pharmaceutical Research and Manufacturers of America, U.S. Rep. Pete Stark provided a synopsis of the scheme implemented by Aventis (Hoechst):

The following chart represents a comparison of Hoechst's fraudulent price representations for its injectable form of the drug versus the truthful prices paid by the industry insider. It is [sic] also compares Hoechst's price representations for the tablet form of Anzemet and the insider's true prices. It is extremely interesting that Hoechst did not create a spread for its tablet form of Anzemet but only the injectable form. This is because Medicare reimburses Doctors for the injectable form of this drug and by giving them a profit, can influence prescribing. The tablet form is dispensed by pharmacists, who accept the Doctor's order. And this underscores the frustration that federal and state regulators have experienced in their attempts to estimate the truthful prices being paid by providers in the marketplace for prescription drugs and underscores the fact that, if we cannot rely upon the drug companies to make honest and truthful representations of their prices, Congress will be left with no alternative other than to legislate price controls.

NDC No:	Unit Size/ Type	Quantity	Net Price as Represented to Florida Medicaid	True Wholesale Price	Variance
0088-1206-32	100 mg/5 ml Injectable	1	\$124.90	\$70.00	Represented price 78% higher than true wholesale price.

(P007548-007588).

7. Additional Evidence Concerning Gammar

281. Similarly, Aventis increased AWP's for its Gammar product line to keep provider and intermediary reimbursement levels competitive with those created by the inflated AWP's of other manufacturers. A May 8, 1996 Aventis (Centeon) Interoffice Correspondence memo states:

Effective June 1, 1996, we will be revising our AVERAGE WHOLESALE PRICE for our Gammar P iv product line. We are implementing this change based on feedback from the field. Alpha and Bayer have recently increased their AWP pricing on

Gammimmune 10% and Venoglobulin S 10%. They are presently priced at \$75 and \$80 per gram respectively. . . . This change will help us maintain a competitive balance in the marketplace.

(ABAWP 004767) (Highly Confidential).

282. Centeon interoffice correspondence, dated June 23, 1999, reveals that a Centeon employee provided a representative of First Data Bank with the following information regarding Centeon's AWP for Gammar:

She asked me to validate Centeon's AWP and wholesale list price for Gammar PIV 5 and 10 gram vials.

I gave her the following info:

"Currently it is not Centeon's business practice to sell Gammar PIV to wholesalers. But should a wholesaler place an order, our wholesale list price is \$52/gram, or \$260 for 5 gram vial, and \$520 for 10 gram vial."

"Centeon's suggested AWP is \$400 for 5 gram vial, and \$800 for 10 gram vial. This is pricing as reported to First Data Bank, but we do not sell product at these prices."

(ABAWP 005315) (Highly Confidential).

283. U.S. Rep. Thomas J. Bliley, in a May 4, 2000 letter to the CEO of Aventis (Behring), also stated concerns regarding Aventis' pricing of Gammar:

The Office of Inspector General (OIG) at the Department of Health and Human Services determined that the Medicare-allowed amount for immune globulin, a pharmaceutical product sold by your company under the name Gammar, in Fiscal Year 1996 was \$42.21. The OIG further estimated that the actual wholesale price of this drug was \$16.12 and the highest available wholesale price that the OIG was able to identify was \$32.11.

(P006962-P006966).

8. Inflated AWP's From Aventis' Price Lists

284. In response to government subpoenas, Aventis produced numerous price lists setting forth spreads between AWP's and prices offered to wholesalers, providers and other

intermediaries. A review of those price lists reveals that Aventis has consistently offered drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers. To repeat every one of those drugs and the spread offered to each specific customer here is not practical.

285. A March 4, 1997 price list issued by Arcola Laboratories (a division of Rhonel-Poulenc Rorer Pharmaceuticals sets the AWP for Calcimar (calcitonin-salmon) at \$31.35, with a cost of \$12.00 – for a spread of 161%. (AV-AAA-000705).

286. As set forth above, Aventis' scheme to inflate its reported AWP's and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

9. Aventis Concealed its AWP Manipulation

287. Aventis deliberately acted to conceal its fraudulent reporting and marketing of the AWP spread. For example, in response to a May 26, 1995 fax request from *Red Book*, Aventis refused to provide Wholesale Acquisition Cost (WAC) for products it listed in the *Red Book* database – in spite of *Red Book's* assurances that WAC information would be distributed via electronic means only. (ABAWP 008420) (Highly Confidential). Aventis effectively hid the AWP spread from Plaintiffs and the Class.

E. Baxter

288. Baxter engages in an organization-wide and deliberate scheme to inflate AWP's. Baxter has stated fraudulent AWP's for all or almost all of its drugs those set forth below. The specific drugs of Baxter for which relief is sought in this case are set forth in Appendix A and are summarized below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
BAXTER	Aggrastat	tirofiban hydrochloride	Glycoprotein Receptor Inhibitor (Blood Modifier) Used in the treatment of acute coronary symptoms
	Ativan	lorazepam	Antianxiety Agent (Psychotherapeutic Agent); Anticonvulsant Used to relieve anxiety and treat insomnia
	Bebulin VH	factor ix (systemic)	Antihemorrhagic Agent Used to treat hemophilia B
	Brevibloc	esmolol hcl	Autonomic Nervous System Agent Used in the treatment of tachyarrhythmias in critical situations
	Buminate	albumin (human)	Plasma Fraction (Blood Modifier) Used in the treatment of hypovolemia and hypoalbuminemia
	Claforan	cephalosporin (systemic)	Antibacterial Agent (Anti-Infective Agent) Used in the treatment of infections caused by bacteria
	Gammagard S/D	immune globulin solution	Antibacterial Agent (Anti-Infective Agent) Used to prevent or treat some illnesses.
	Gentran	dextran	Blood Derivative; Blood Modifier Used in the emergency treatment of shock
	Holoxan/Ifex	ifosfamide	Antineoplastic Used in the treatment of various forms of cancer
	Iveegam EN	immune globulin iv	Antibacterial Agent (Anti-Infective Agent) Used as replacement therapy in patients with primary immunodeficiency syndromes
	Osmitol	mannitol	Osmotic Diuretic Used to promote diureses during treatment of acute kidney failure. Also used to reduce intraocular and intracranial pressure
	Recombinate	factor viii	Antihemophilic Factor Used to induce blood clotting
	Travasol	amino acid	Dietary Supplement Used for nutritional support in cancer patients
	Vancocin HCl	vancomycin hydrochloride	Antibacterial Agent (Anti-Infective Agent) Used in the treatment of infections caused by bacteria
		cisplatin	Antineoplastic Used to treat cancer of the bladder, ovaries, and testicles
		dextrose	Caloric Agent; Electrolyte Replenisher Used to increase intake of calories and fluids

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
		doxorubicin hcl	Antineoplastic Used in the treatment of various forms of cancer
		gentamicin	Antibacterial Agent (Anti-Infective Agent) Used to treat serious bacterial infections
		heparin	Anticoagulant (Cardiovascular Agent) Used to decrease the clotting ability of the blood
		sodium chloride	Flush; Abortifacient Used to remove medicine and blockage from intravenous (IV) catheter. Also used to induce abortion

1. Baxter Has Been the Target of Government Investigations

289. Baxter has been investigated by the United States Department of Justice, Department of Health and Human Services Office of Inspector General, the Attorney General for the State of California, the Attorney General for the State of Texas, the Attorney General for the State of Illinois, and the Committee on Commerce of the House of Representatives.

290. These investigations confirm that Baxter has engaged in a deliberate scheme to inflate AWP's for many or most of its drugs. A Baxter document made public as a result of the congressional investigation entitled, "Confidential – Baxter Internal Use Only," acknowledged that: "Increasing AWP's was a large part of our negotiations with the large homecare companies." Baxter further admitted in internal documents that homecare companies that reimburse based on AWP make a significantly higher margin. Thus, Baxter's own documents demonstrate its active participation in the scheme to artificially inflate AWP's.

2. Baxter's Definition and Understanding of AWP

291. Despite its manipulation, Baxter understood what AWP should mean: "The average price that a pharmacy (or provider) pays for the product from their drug wholesaler or distributor." (BAX MDL 0011378) (Highly Confidential). Contrary to its own definition of

AWP, Baxter nonetheless set AWP for its drugs far in excess of what providers paid for those drugs.

3. Baxter Controls the Published AWP for its Products

292. Baxter has controlled and set the AWP for its pharmaceutical products through direct communications with industry compendia during the Class Period. For example, a September 7, 1995 inter-office memorandum provides:

I have been in contact with both *Red Book* and Medispan earlier this year about our AWP. I told them that we will not be raising our AWP for FVIII in 1995, and will only increase IGIV in the event of a label change. There are a few general rules about AWP adjustments.

- A manufacturer may raise AWP at any time in the year. There is a monthly publication called the *Red Book* Update that lists all changes to the April publication (the big red book).
- If a manufacturer does decide to increase AWP: - payors want a justification for the increase. This is why we typically don't increase the AWP unless we have a label change, product enhancement

(BAX MDL 0004754) (Highly Confidential).

4. Baxter's AWP Manipulation Benefited Providers at the Expense of the Class

293. In at least one internal document, Baxter recognized that deliberate manipulation of the spread was being wrongly used to gain competitive advantage by manufacturers:

The deliberate manipulation of AWP or WAC prices is a problem that we need to address. The spread between acquisition cost and AWP/WAC is direct profit for customers, and is being used to increase product positioning in the market by certain manufacturers.

(BAX MDL 0012778) (Highly Confidential) (emphasis added).

294. Despite this recognition, Baxter nonetheless continued to manipulate its AWP in order to maintain the competitiveness of its own products based upon the spread. In a January 6,

1992 inter-office memorandum, Baxter informs its employees how to respond to inquiries concerning AWP increases for Baxter products:

If you receive inquiries from customers or payors questioning our rationale on this recent increase in Published AWP for Baxter products please communicate the following message and no more.

If any further information is needed please send the inquiry to me directly.

A recent review of industry published direct prices and AWP's revealed that Baxter's published AWP's are significantly lower than competitive AWP's. We have therefore adjusted our AWP's to meet competitive levels.

Most of Baxter General Healthcare Division's products are sold to distributors at negotiated contract prices that are different from AWP's. We do not have knowledge of or input to the actual prices charged to the provider by our distributors. The contracted prices to our distributors will not be directly affected by this change in AWP's.

(BAX MDL 0004210) (Highly Confidential).

295. In addition, Baxter's marketing and sales documents, which were prepared and disseminated to its employees and agents via the U.S. mail and interstate wire facilities, compared the costs of their respective drugs to those of their respective competitors and were intended to induce physicians to use Baxter drugs and shift market share in its favor. Other documents created and disseminated by Baxter compared the AWP and the actual "cost" of their respective drugs, so that medical providers could easily see the different "return-to-practice" amounts available for different levels of purchase.

5. Specific Baxter AWP's Documented by the DOJ

296. In a report published by the DHHS (AB-00-86), the DOJ documented at least 41 instances where the published AWP's for various dosages of drugs manufactured by Baxter were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the four drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular

dosage, based upon wholesalers' price lists, with the AWP reported by Baxter in the 2001 *Red Book*.

Drug in Lowest Dosage Form	Baxter's 2001 <i>Red Book</i> AWP	DOJ Determined Actual AWP	Difference	Percentage Spread
Dextrose	\$928.51	\$2.25	\$926.26	41,167%
Dextrose Sodium Chloride	\$357.69	\$2.93	\$354.76	12,108%
Sodium Chloride	\$928.51	\$1.71	\$926.80	54,199%
Factor VIII	\$1.28	\$.92	\$.36	39%

(P006299-006316).

6. Evidence Concerning Gammagard S/D (immune globulin solution)

297. Baxter admittedly manipulated the AWP for Gammagard S/D. In 1996, Baxter distributed a memo providing "[t]he deliberate manipulation of AWP or WAC prices is a problem that we need to address. The spread between acquisition cost and AWP/WAC is a direct profit for customers, and is being used to increase product positioning in the market by certain manufacturers." Immediately below this text is a handwritten note reading "[w]ill raise AWP for GG/SD by 15%." (BAX MDL 0012778) (Highly Confidential).

298. According to Baxter's own documents, the published AWP's for Gammagard S/D were higher than the actual prices provided to wholesalers. In a customer announcement dated September 24, 1996, Baxter increased the AWP for one particular dosage of Gammagard S/D from \$640.71 to \$737.00, and the WAC from \$365.00 to \$420.00. The difference between the new AWP and the new WAC (\$317.00) constituted a 43% spread. (BAX MDL 005366) (Highly Confidential).

7. Inflated AWP's From Baxter's Price Lists

299. In response to government subpoenas, Baxter produced numerous price lists setting forth spreads between AWP's and prices apparently offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that Baxter has consistently offered hundreds of its drugs and other solutions to its customers at prices significantly below the

published AWP and that the spread was of great importance to its customers. To repeat every one of those drugs and the spread offered to each specific customer here is not practical. However, set forth below in Tables 1 and 2 are a number of those drugs (not already referenced above) with spreads between the AWP's and direct prices. Table 1 is an analysis of certain dosages of Baxter drugs from a document entitled "Baxter Healthcare Corporation Intravenous and Irrigation Solution Products Report" (BAX MDL 0003428-46) (Highly Confidential)).

Table 1

Drug	AWP	DP	Difference	% Spread
Ringers	10.84	6.34	4.50	71%
Lactated Ringers	12.36	7.43	4.93	66%
Plasma-lyte 148	15.67	10.85	4.82	44%
5% Traver and electrolyte no. 2	16.39	11.30	5.09	45%
6% Gentran75	73.46	33.19	40.27	121%
Sterile Water	9.97	6.15	3.82	62%
Sodium Lactate	17.98	11.11	6.87	62%
Osmitrol	70.28	35.12	35.16	100%
Gentamycin	10.78	7.25	3.53	49%
Metronidazole injection	15.34	7.85	7.49	95%
Rocephin	40.18	32.67	7.51	23%
Nitroglycerin	17.37	9.82	7.55	77%
Potassium Chloride Injection	14.63	10.16	4.47	44%
Dopamine	19.30	13.40	5.90	44%
Lidocaine	22.74	13.48	9.26	67%
Heparin	9.94	6.49	3.45	53%
Theophylline	11.45	7.81	3.64	47%
Glycine for Irrigation	32.87	19.70	13.17	67%
Tis-U-Sol	22.73	11.36	11.37	100%
Acetic Acid	20.70	10.91	9.79	90%
Irrigating Solution G	16.67	11.04	5.63	51%
Balanced Salt Solution	28.76	15.00	13.76	92%
Sodium Bicarbonate	39.23	16.36	22.87	140%

300. Table 2 is an analysis of certain dosages of Baxter drugs from a document entitled "IV Nutrition Products" (BAX MDL 0003421-26) (Highly Confidential).

Table 2

Drug	AWP	DP	Difference	% Spread
Novamine Injection	95.14	51.48	43.66	85%
Travasol	83.44	40.21	43.23	108%
RenAmin Injection	75.00	48.00	27.00	56%

Aminess Essential Amino Acid	107.35	66.00	41.35	63%
BranchAmin Injection	93.60	60.00	33.60	56%

8. Baxter Provided Free Goods and Other Incentives

13. Baxter also provided physicians with free goods with the understanding that physicians would bill for those goods, in violation of federal law. Billing for free goods was a way for physicians to obtain greater profit at the expense of the Class. Baxter's fraudulent use of free goods aimed at increasing market share is evidenced by an internal memorandum from a Baxter contract administrator to certain field sales managers encouraging the distribution by U.S. mail or otherwise of free product to achieve overall price reduction:

BAXTER: "The attached notice from Quantum Headquarters was sent on April 10th to all their centers regarding the reduction on Recombinate pricing. Please note that they want to continue to be invoiced at the \$.81 price. They have requested that we send them free product every quarter calculated by looking at the number of units purchased in that quarter and the \$.13 reduction in price . . . free product given to achieve overall price reduction."

Letter from Stark, Committee on Ways and Means to Holman, Pres. Pharmaceutical Research and Manufacturers of America, Sept. 28, 2002 (P0075410-44).

301. As set forth above, Baxter's scheme to inflate its reported AWP's, market the resulting spread, and channel to providers "free" goods – all in order to increase the market share of its drugs – has resulted in excessive overpayments by Plaintiffs and the Class.

F. Bayer

302. Bayer engages in an organization-wide and deliberate scheme to inflate AWP's. Bayer has stated fraudulent AWP's for all or almost all of its drugs, including those set forth below. The specific drugs of Bayer for which relief is sought in this case are set forth in Appendix A, and are set forth below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
BAYER	Cipro	ciprofloxacin or ciprofloxacin hcl	Antibiotic Agent (Anti-Infective Agent) Used in the treatment of various bacterial infections, including anthrax
	Cipro XR	ciprofloxacin hcl- ciprofloxacin betaine	Antibiotic Agent (Anti-Infective Agent) Used in the treatment of various bacterial infections, including anthrax
	DTIC-Dome	dacarbazine	Antineoplastic Used in the treatment of melanoma and Hodgkin's disease
	Gamimune N	immune globulin (human) iv	Immunizing Agent Used as maintenance therapy in patients with compromised immune systems
	Koate-HP	antihemophilic factor (human)	Antihemophilic Factor (Blood Modifier) Used to increase blood clotting and decrease bleeding episodes
	Kogenate	antihemophilic factor (recombinant)	Antihemophilic Factor (Blood Modifier) Used to increase blood clotting and decrease bleeding episodes
	Mithracin	plicamycin	Antineoplastic; Antihypercalcemic Agent Used in the treatment of various forms of cancer

1. Bayer Has Been the Target of Government Investigations

303. In connection with its scheme to inflate AWP's, Bayer has been investigated by the Department of Justice, Department of Health and Human Services, Office of Inspector General, and the Commonwealth of Massachusetts. Bayer agreed to settle claims asserted by the United States government and 47 states arising from its fraudulent pricing and marketing practices. According to the DOJ's January 23, 2001 press release:

The government's investigation of the allegations...revealed that [Bayer] beginning in the early 1990s, falsely inflated the reported drug prices – referred to by the industry as the Average Wholesale Price (AWP), the Direct Price and the Wholesale Acquisition Cost – used by state governments to set reimbursement rates for the Medicaid program. By setting an extremely high AWP and, subsequently, selling drugs at a dramatic discount, Bayer induced physicians to purchase its products rather than those of competitors by enabling doctors to profit tremendously from reimbursement paid to them by the government.

The Bayer AWP's at issue in the investigation involved Bayer's biologic products such as Kogenate, Koate-HP, and Gamimmune, which are widely used in treating hemophilia and immune deficiency diseases. The investigation further revealed that the practice in which Bayer selectively engaged, commonly referred to as "marketing the spread," also had the effect of causing other drug companies to inflate their AWP's.

"Bayer Corporation Settlement on Medicaid Drug Prices" (P011236-011237).

304. As part of its settlement of government claims in 2000, Bayer is required, under the terms of a corporate integrity agreement, to provide state governments and the federal government with the average selling prices of its drugs – a price which accounts for all discounts, free samples, rebates and all other price concessions provided by Bayer to any relevant purchaser that result in a reduction of the ultimate cost to Bayer's customers.

305. In April 2003, Bayer also agreed to pay the government \$251.6 million in civil penalties for violating the Federal Prescription Drug Marketing Act for alleged overcharges involving its antibiotic Cipro and its high blood pressure drug Adalat.

2. Bayer Controls the Published AWP for Its Products

306. Bayer has controlled and set the AWP's for its pharmaceutical products through direct communications with industry compendia during the Class Period. In one internal marketing memorandum, Bayer stated:

I would like to formally request that you contact Redbook and request an AWP change for all sizes (670-20, 670-30, 670-50) of Kogenate from \$1.18 per IU to \$1.24 per IU to match Baxter's increase. I have attached a letter from Baxter to Redbook outlining their price change request. (Prior to making the change in AWP for Kogenate, please confirm with Redbook that Baxter has indeed initiated a price change.)

(BAY005278) (Highly Confidential).

3. Bayer's AWP Manipulation Benefited Providers at the Expense of the Class

307. As detailed in a September 28, 2000 letter from Representative Stark to Alan F. Holmer, President of the Pharmaceutical Research and Manufacturers of America, internal Bayer

documents reveal Bayer knowingly participated and directed the scheme to artificially inflate the AWP for its products and to market the spread:

BAYER: "Chris, if Baxter has increased their AWP then we must do the same. Many of the Homecare companies are paid based on a discount from AWP. If we are lowed [sic] than Baxter then the return will be lower to the HHC. It is a very simple process to increase our AWP, and can be done overnight."

(P007549.)

308. Tom Bliley, in a letter dated September 25, 2000 to the Health Care Financing Administration, analyzed drug sales in Florida and noted that sales of Bayer's WhinRho "skyrocketed" when competitors reduced their spreads but Bayer did not.

4. Specific Bayer AWP Documented by the DOJ

309. In a report published by the DHHS, the DOJ documented at least 10 instances where the published AWP for various dosages of two drugs manufactured by Bayer were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the two drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by Abbott in the 2001 *Red Book*.

Drug	Bayer's 2001 <i>Red Book</i> AWP	DOJ Determined Actual AWP	Difference	Percentage Spread
Immune Globulin	\$450.00	\$362.50	\$87.50	24%
Factor VIII	\$0.92	\$0.42	\$0.50	119%

(AB-00-86 (P006299-006316)).

310. In a DHHS OIG report (*see* OEI-03-00-00310 (P006398-006424)), the government also discovered that the AWP for all immune globulin pharmaceuticals (of a dosage of 5g), including Bayer's Gamimune® (Bayer was one of five manufacturers of the dosage listed in the 1997 *Red Book*), were over inflated by an average spread of 32.21%.

311. According to the government's settlement with Bayer arising out of Bayer's fraudulent pricing and marketing practices, the Bayer AWP's at issue in the investigation (and ultimately settled) include the AWP's for Kogenate.

5. Inflated AWP's From Bayer's Price Lists

312. According to Bayer's own documents, the published AWP's for its drugs were higher than the actual prices provided to wholesalers. In response to government subpoenas, Bayer produced numerous price lists setting forth spreads between AWP's and prices apparently offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that Bayer has consistently offered hundreds of its drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers.

6. Bayer Provided Free Goods and Other Incentives

313. In addition to marketing the spread, Bayer has utilized other impermissible inducements to stimulate sales of its drugs. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price. By utilizing "off-invoice" inducements, Bayer provided purchasers with substantial discounts meant to gain their patronage while maintaining the fiction of a higher wholesale price.

314. Evidence of these practices is found in an October 1, 1996 Bayer internal memorandum addressing volume sales opportunities for the pharmaceutical Kogenate®:

BAYER: "I have been told that our present Kogenate price, \$.66 is the highest price that Quantum is paying for recombinant factor VIII. In order to sell the additional 12mm/u we will need a lower price. I suggest a price of \$.60 to \$.62 to secure this volume. From Quantum's stand [sic] point, a price off invoice, is the most desirable. We could calculate our offer in the form of a marketing grant, a special educational grant, payment for specific data gathering regarding Hemophilia treatment, or anything else that will produce the same dollar benefit to Quantum Health Resources."

315. As set forth above, Bayer's scheme to inflate its reported AWP's and market the resulting spread to increase the market share of its drugs and its use of other "off invoice" rebates and financial inducements to its customers has resulted in excessive overpayments by Plaintiffs and the Class.

316. Bayer routinely offered its customers off-invoice discounts as one feature of its standard contracts. (BAYM002428).

7. Bayer Concealed Its AWP Manipulation

317. Bayer deliberately acted to conceal its fraudulent reporting and marketing of the AWP spread. Bayer routinely required that its customers keep secret the prices they were being charged for Bayer drugs. (BAYM000913, BAYM002436).

G. The Boehringer Group

318. The Boehringer Group engages in an organization-wide and deliberate scheme to inflate AWP's. The Boehringer Group has stated fraudulent AWP's for all or almost all of its drugs, including those set forth below. The specific drugs of The Boehringer Group for which relief is sought in this case are set forth in Appendix A and are identified below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
BOEHRINGER GROUP (Boehringer, Ben Venue, Bedford and Roxane)	Viramune	nevirapine	Antiviral Agent (Anti-Infective Agent) Used in the treatment of HIV infection
		acycolvir sodium	Anti-Infective Agent Used in the treatment of herpes infections
		amikacin sulfate	Antibiotic Agent (Anti-Infective Agent) Used to treat respiratory tract, urinary tract, bone, skin and soft tissue infections
		cytarabine	Antineoplastic Used to treat leukemia and non-Hodgkin's lymphoma
		doxorubicin hydrochloride	Antineoplastic Used in the treatment of ovarian cancer and AIDS-related Kaposi's sarcoma

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
		etoposide	Mitotic Inhibitor (Antineoplastic) Used in the treatment of testicular neoplasm and small cell cancer of the lung
		leucovorin calcium	Antianemic Agent (Blood Modifier) Used in the treatment of anemia
		methotrexate sodium	Antineoplastic Used in the treatment of various forms of cancer
		mitomycin	Antineoplastic Used in the treatment of various forms of cancer
		vinblastine	Antineoplastic Used in the treatment of various forms of cancer, including lymphoma and breast cancer
		vinblastine sulfate	Antineoplastic Used in the treatment of various forms of cancer, including lymphoma and breast cancer

1. The Boehringer Group Has Been the Target of Government Investigations

319. In connection with its scheme to inflate AWP's, The Boehringer Group has been investigated by the Department of Justice, the Department of Health and Human Services Office of Inspector General, the Committee on Commerce of the House of Representatives, and the Nevada Attorney General.

2. The Boehringer Group Controls the Published AWP for Its Products

320. The Boehringer Group has controlled and set the AWP's for its pharmaceutical products through direct communications with industry compendia during the Class Period. For example, a September 27, 1996 document entitled "*Red Book* Product Listing Verification" required Defendant to sign each page that contained a list of The Boehringer Group's products, NDC numbers, AWP's, WAC's and price effective dates. (MDL BV 000799). Similarly, a *Red Book* New Product Information Form dated November 25, 1996 was completed by Bedford for

the drug Ketamine Hydrochloride Injection USP and required Bedford to fill in the AWP and WAC for the product (which it did). (MDL BV 000807).

321. Despite its actual verification of the AWP's in the *Red Book*, The Boehringer Group claims that it does not set "AWP's" but nonetheless agrees that the "terms 'average' and 'wholesale' are the standard dictionary definitions." In a letter dated August 20, 1999 to the Chairman of the Committee on Commerce regarding "Response to Request for Pricing Information, July 19, 1999" ("Bedford's AWP Response"), counsel for Bedford Laboratories stated as follows:

Please provide all definitions of AWP used by your company since January 1, 1996 for the purpose of determining the reimbursement price for Medicare-covered drugs, and all records relating to those definitions. In particular, please provide the specific definitions you apply to the terms "average" and "wholesale."

Answer: The term "AWP", which we interpret as meaning Average Wholesale Price, is not used by Bedford Laboratories in pricing any of its products. Moreover, Bedford has not and does not take into account the "reimbursement price for Medicare-covered drugs" in pricing any of its products. Rather than use AWP, Bedford established a Hospital Price List for its products. The Hospital Price List refers to the price a customer without a contract, who is not a wholesaler or distributor, would pay for Bedford's products. It also refers to a suggested price that a wholesaler charges its customers. This terminology is used because the majority of Bedford's customers, particularly for drugs such as Leucovorin, are hospitals.

The pharmaceutical reporting services, such as Redbook, independently identify Bedford's Hospital Price List as AWP. The prices Bedford charges its wholesale customers are referred to at Bedford as Wholesale Price Lists, which are identical for all of Bedford's wholesale customers. These prices are identified by the pharmaceutical reporting services as Wholesale Acquisition Cost ("WAC"). *Given its pricing terminology and practices, Bedford's definitions of the terms "average" and "wholesale" are the standard dictionary definitions."*

(MDL BV 001941-1944, at 1941-1942) (Confidential) (emphasis added).

322. Notwithstanding its attempt to distance itself from its published AWP's, The Boehringer Group effectively ratified the AWP's set by its predecessors. In Bedford's AWP Response, counsel responded:

... Bedford performs no AWP calculation for Leucovorin, 50 mg and did not do so during calendar year 1998. ... This price was established by Chiron Therapeutics, which prior to May, 1996, had the marketing responsibilities for this product. Bedford took over those responsibilities in May of 1996 and continued the price established by Chiron. Prior to that time, Ben Venue, Bedford's parent, only manufactured this product. For that reason, Bedford is not aware of how Chiron originally priced this product.

(MDL BV 001941-1944, at 1942) (Confidential) (emphasis added).

323. Of course, depending on which government entity was performing the investigation and the date of the government's inquiries, The Boehringer Group's "definition" of AWP changed. By November 2, 1999, Bedford told the Committee on Commerce that it understood AWP to be tied to "the manufacturer's suggested prices to customers of its customers." (MDL BV 006761-65, at 6763).

324. In a letter dated June 5, 2000 to the Nevada Attorney General regarding the Attorney General's inquiries about Bedford's AWP, Bedford responded in pertinent part:

1. Identify what Bedford represents to be its understanding of the meaning "AWP."

Answer: Bedford's understanding of AWP, derived from its experience in the industry, is that it is a suggested price identified by pharmaceutical companies as the price a wholesaler may wish to charge its customers for pharmaceutical products. Bedford has always viewed AWP as a suggested 'retail' price to the customers of wholesalers and not as an acquisition cost to wholesalers.

2. Does Bedford report AWP to First Databank for all its products? With what frequency? How is that information communicated?

Answer: Bedford does not use the term AWP in its business, *except as a semantical concession* to those who, like the price reporting services, have reported Bedford's Hospital List Price ("HLP") as an AWP. Upon request by FDB, Bedford provides its

price lists, which consist of the HLPs and Wholesale List Prices ("WLPs") for its products. ****

Bedford reports this information, usually by facsimile, at least once a year, and more frequently upon request by FDB.

(MDL BV 002071-73, at 2072) (Confidential) (emphasis added).

325. In fact, even armed with the knowledge that industry compendia use Bedford's HLPs as AWP, Bedford admits that HLPs do not accurately reflect the AWP for its drugs:

As indicated above, Bedford does not communicate AWP for its products. However, it is aware that pharmaceutical price reporting services have chosen to report Bedford's HLP as AWP. Bedford has always reported its HLP accurately. *These list prices are not averages of the wholesale prices for Bedford's products.*

(MDL BV 002071-73, at 2073) (emphasis added).

326. In practice, Bedford did in fact acknowledge that its HLPs should be used as AWP in the industry compendia. For example, a June 17, 1996 fax cover sheet from Bedford to Medispan states: "[S]ee corrections noted for select products on the AWP cost!" (MDL BV 000770) (Confidential). Attached to this cover sheet is Bedford's Hospital Price List dated May 1, 1996 in which certain prices are crossed out and replaced with typewritten prices. (MDL BV 000771-780) (Confidential). Similar cover sheets with the same notation and the same price lists were also sent to First Data Bank (MDL BV 000774-780, MDL BV 000781-785) (Confidential) ("[S]ee corrections made on select products for the AWP!") and *Red Book* (MDL BV 000793-95) (Confidential) ("Corrections made on the AWP for select products!").

3. Specific Boehringer AWP Documented by the DOJ

327. In a report published by the DHHS, the DOJ documented at least 32 instances where the published AWP for various dosages of nine drugs manufactured by The Boehringer Group were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the nine drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for

that particular dosage, based upon wholesalers' price lists, with the AWP reported by The Boehringer Group in the 2001 *Red Book*.

Drug	The Boehringer Group's 2001 <i>Red Book</i> AWP	DOJ Determined Actual AWP	Difference	Percentage Spread
Acyclovir Sodium	\$ 528.00	\$ 207.00	\$ 321.00	155%
Amikacin Sulfate	\$ 437.50	\$ 65.33	\$ 372.17	570%
Mitomycin	\$ 128.05	\$ 51.83	\$ 76.22	147%
Cytarabine	\$ 62.50	\$ 3.55	\$ 58.95	1,661%
Doxorubicin HCL	\$ 945.98	\$ 139.75	\$ 806.23	577%
Etoposide	\$ 110.00	\$ 8.45	\$ 101.55	1,202%
Leucovorin Calcium	\$ 184.40	\$ 2.76	\$ 181.64	6,581%
Methotrexate Sodium	\$ 68.80	\$ 2.63	\$ 66.17	2,516%
Vinblastine Sulfate	\$ 212.50	\$ 8.19	\$ 204.31	2,495%

4. Inflated Boehringer Group AWP's From Bedford's Price Lists

328. According to Bedford's own documents, the published AWP's for the drugs listed above by the DOJ were, in fact, higher than the actual prices provided to wholesalers. In response to government subpoenas, Bedford produced several price lists setting forth spreads between AWP's and prices apparently offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that Bedford has consistently offered the above drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers. (MDL BV 000799-806).

329. As set forth above, The Boehringer Group's scheme to inflate its reported AWP's and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

H. B. Braun

330. B. Braun engages in an organization-wide and deliberate scheme to inflate AWP's. B. Braun has stated fraudulent AWP's for all or almost all of its drugs, including those set forth

below. The specific drugs of B. Braun for which relief is sought in this case are set forth in Appendix A and identified below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
B. BRAUN		dextrose	Caloric Agent; Electrolyte Replenisher Used to increase intake of calories and fluids
		dextrose in lactated ringers	Caloric Agent; Electrolyte Replenisher Used to increase intake of calories and fluids
		dextrose w/ sodium chloride	Caloric Agent; Electrolyte Replenisher Used to increase intake of calories and fluids
		heparin sodium (porcine) in d5w	Blood Modifier Used to treat and prevent thrombosis and pulmonary embolism
		sodium chloride	Flush; Abortifacient Used to remove medicine and blockage from intravenous (IV) catheter. Also used to induce abortion
		sodium chloride (gu irrigant)	Flush; Abortifacient Used to remove medicine and blockage from intravenous (IV) catheter. Also used to induce abortion

1. B. Braun Has Been the Target of Government Investigations

331. In connection with its scheme to inflate AWP's, B. Braun has been investigated by the United States Department of Justice, the Office of Inspector General of the Department of Health and Human Services, the Attorney General for the State of Texas, and the Attorney General for the State of California.

2. B. Braun's Understanding of AWP

332. Undated notes made in conjunction with a meeting held to address a customer's concerns about B. Braun's decision to increase AWP's for a number of drugs reveals B. Braun's understanding of AWP's:

Let Rob know that most products are already (AWP's) above wholesaler prices. Make him understand that AWP's are based on not what prices they buy it at but at what price they This

doesn't matter as for as setting AWP's it is not what the wholesaler sells the products for that set the AWP price (average sell prices).

B. Braun's documents prove that it knew that customers – and members of the Class – understood AWP's to be related to average wholesale prices. (BBMDL 001907) (Highly Confidential).

3. B. Braun Controls the Published AWP for Its Products

333. B. Braun has controlled and set the AWP's for its pharmaceutical products through direct communications with industry compendia during the Class Period.

a. A September 11, 1995 McGaw (acquired by B. Braun in 1997) internal memorandum addresses the company's recognition of its ability to control the published AWP:

Below I have listed all data base companies the specific percentage mark-up that they apply to our "list" prices:

First Data Bank	20%
Medispan	25%
Redbook	Whatever we want them to publish
Facts & Comparisons	Information on our products should be submitted to this company although they do not publish pricing, only clinical data

Connie, when we submit our list and AWP prices to these companies this year, let's submit a mark-up of 25% above our list prices to all companies so it will be consistent.

(BBMDL 000013) (Highly Confidential).

b. Notes from an October 1994 telephone conversation between a representative of *Red Book* and McGaw provide further proof that B. Braun understood it could unilaterally control its AWP's:

Spoke to Roni Lane at Redbook. She did not know why Baxter not listed in OTC section. She said we can send her whatever price for AWP we want and she will have it published.[] If we increase AWP prices we can send her only AWP to have published ad not list so spread between the 2 won't show. No one regulates pricing